K080043

AUG 22 2008

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-2458

Contact Person: Stephanie Greeman

Date Prepared: March 5, 2008

Device Name

Proprietary name: Elecsys Anti-TSHR CalCheck

Common name: Anti-TSHR CalCheck

Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys Anti-TSHR CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys C-Peptide CalCheck (K040157).

Device Description

The Elecsys Anti-TSHR CalCheck is a lyophilized product consisting of human anti-TSHR antibodies in human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

Intended use

For use in the verification of the calibration established by the Elecsys Anti-TSHR reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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Comparison Table

The table below compares Elecsys Anti-TSHr CalCheck with the predicate device, Elecsys C-Peptide Calcheck (K040157).

Characteristic	Elecsys C- Peptide CalCheck (K040157)	Elecsys Anti-TSHR CalCheck
Intended Use	For use in the verification of the calibration established by the Elecsys C-Peptide reagent on the indicated Elecsys and **cobas** e immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Anti-TSHR reagent on the indicated Elecsys and **cobas** e immunoassay analyzers.
Levels	Three	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mixing gently.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20 – 25 °C : 4 hrs	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 15 - 25 °C : 5 hrs
Matrix	equine serum matrix	Human serum

Performance Characteristics

The Elecsys Anti-TSHR CalCheck was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics
c/o Ms. Stephanie Greeman
9115 Hague Road
Indianapolis, IN 46250

AUG 22 2008

Re: k080643
Trade Name: Elecsys Anti-TSHR CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Codes: JJX
Dated: July 29, 2008
Received: July 31, 2008

Dear Ms. Greeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K080643

Device Name: **Elecsys Anti-TSHR CalCheck**

Indication For Use:

For use in the verification of the calibration established by the Elecsys Anti-TSHR reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080643